UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/303,315	04/30/1999	EUGENE S. PEARLMAN	108604/002	8170

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EXAMINER
ZEMAN, MARY K

ART UNIT	PAPER NUMBER
1631	13

DATE MAILED: 03/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

	Application No.	Applicant(s)
Office Action Summary	09/303,315	PEARLMAN, EUGENE S.
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- *Th* MAILING DATE *of this communication appears on th* cov *r sheet with the correspondenc* address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _19 December 2001_ .

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-11 and 13-25_ is/are pending in the application.

4a) Of the above claim(s) _5-17,19,20 and 25_ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-4,18 and 21-24_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)   4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)   5) ☐ Notice of Informal Patent Application (PTO-152)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .   6) ☐ Other: .

DETAILED ACTION

Claims 1-11 and 13-25 are pending in this application. Claims 5-11, 13-17, 19 and 20 stand withdrawn from consideration as being drawn to non-elected species. Claim 25 is newly added and is also drawn to a non-elected species, a lupus algorithm, and is therefore withdrawn. All pending claims have been significantly amended. Claim 18 is now the only originally examined claim drawn to the elected species, hepatitis.

Applicant's arguments filed 12/19/01 have been fully considered but they are not completely persuasive. Any rejections not repeated below have been withdrawn.

Rejections Maintained

Claim 22 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is unclear as to its significance- how does the limitation that the tests are equal in data size further limit the apparatus? Applicant did not respond to this rejection in the response.

Claims 1-4 and 21-24 remain rejected under 35 U.S.C. 102(e) as being anticipated by Armstrong et al. (US 6,099,469).

Applicants arguments are drawn to limitations not present in the above rejected claims. Applicant's arguments are directed to improvements over the particular cardiac algorithm disclosed by Armstrong, however it is the *generic* claims (i.e. not specifically directed to myocardial infarction) that have been rejected. The disclosure of Armstrong meets the limitations of the steps set forth in the *generic* claims rejected above, and the apparatus of Armstrong meets all the limitations of the *generic* apparatus rejected above. Applicant's arguments regarding the need for technician input, or time variables are not persuasive, as the rejected claims do not exclude any input from any outside source, nor do they indicate that they cannot be run repeatedly. The rejected claims set forth open claim language, allowing for the addition of additional steps and limitations.

As set forth previously, Armstrong et al. (US 6,099,469) disclose a disease specific algorithm for use in a computer assisted method, which analyzes what clinical tests should be performed. The particular disease state of Armstrong et al. is acute myocardial infarction. A first test is performed on the sample, then, based upon the result of that test in comparison with preset guidelines, a second test is run. This process is repeated until an endpoint is reached. That endpoint is a diagnosis of a condition (columns 4-11 specifically describe the tests, etc.). Figures 1B-1F set forth the decision tree of clinical tests and diagnoses used in the particular algorithm for the disease state. Figure 2, and the discussion from column 11 line 30 to column 14, line 25, set forth various systems and apparati for performing the method. Therefore, the disclosure of Armstrong et al. meet the limitations of the above rejected claims.

Claims 1-4 and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Carlson et al. (US 6,140,065).

Applicant's arguments regarding Carlson are directed to limitations not present in the rejected claims. Applicant argues that the invention offers improvement over the particular prostate cancer algorithm disclosed by Carlson, however, however it is the *generic* claims (i.e. not specifically directed to prostate cancer) that have been rejected. The disclosure of Carlson meets the limitations of the steps set forth in the *generic* claims rejected above, and the apparatus of Carlson meets all the limitations of the *generic* apparatus rejected above.

As set forth previously, Carlson et al. (US 6,140,065) disclose computer assisted methods for diagnosing a disease state based upon a reflex algorithm. The particular disease state of Carlson et al. is prostate disease. The particular algorithm of Carlson et al. differentially diagnoses between benign prostate diseases and prostate adenocarcinomas. Columns 2-4 discuss the particulars of the diagnostic algorithm, and the claims set forth a detailed diagnostic algorithm to be used. The paragraph bridging columns 3 and 4 set forth a system or apparatus for performing the algorithm. Therefore, Carlson et al. meet the limitations of the above rejected claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 18 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Adlassnig et al. (1995). This is a new grounds of rejection based solely on Applicant's amendments to the claims.

The pending claims have been amended to recite methods of diagnosis using programming algorithms wherein the tests to be performed are defined, then run sequentially on clinical samples. The normal values of the tests are compared to the values obtained on the sample, and from analysis of the results, a diagnosis is obtained. Claim 18 recites the particulars of the algorithm for the diagnosis of HBV infection.

Adlassnig et al. (Artificial Intelligence in Medicine, 1995, Vol. 7, pages 1-24) disclose the HEPAXPERT-I computer algorithm which is useful in obtaining a diagnosis of HBV infection. Figures 2 and 3 set forth the typical serology for a variety of types of HBV infections, therefore identifying what clinical tests should be used for the diagnosis. The tests include HbsAg, HbsAb, HbeAg, etc. A number of algorithm rules based upon the normal, and typical scenarios of HBV infection are written into the computer memory (Tables 1 and 2). (All computers use bit-words of various lengths, and this is not a novel feature of the invention.) The computer goes through all the tests and combinations, which can be repeated, until a diagnosis is established. The programmed computers of Adlassnig et al. meet the limitations of the generic apparatus claims, as memory, a processor, and software are all present. Therefore, Adlassnig et al. meets the limitations of the above rejected claims.

Claims 1-4, 18 and 21-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Pearlman et al. (1998). This is a new grounds of rejection based solely on Applicant's amendments to the claims.

The pending claims have been amended to recite methods of diagnosis using programming algorithms wherein the tests to be performed are defined, then run sequentially on clinical samples. The normal values of the tests are compared to the values obtained on the sample, and from analysis of the results, a diagnosis is obtained. Claim 18 recites the particulars of the algorithm for the diagnosis of HBV infection.

Pearlman et al. (Clin. Lab. Manage. Rev. 1998 (July-August) Vol. 12, No. 4, pages 243-247) disclose in Figure 2 a diagnostic algorithm for the diagnosis of HBV, (among other hepatitis related illnesses) wherein a variety of tests are sequentially performed on the sample, compared to normal values, and depending on the results, other tests are performed until a diagnosis is made. The tests performed include HbsAg, HbsAb, HbeAg, etc. Pearlman also disclose cost-benefit analyses of the algorithm in the discussion and Table 2. The programmed computers of Pearlman meet the limitations of claims 21-24. Therefore, Pearlman et al. meet the limitations of the above rejected claims. This publication has a differing inventive entity than the instant application, has an earlier publication date that the filing date of the instant invention, and is therefore properly a reference under 102(a).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this

final action.

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The
examiner can generally be reached between the hours of 7:00 am and 1:00 pm Monday through
Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's
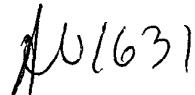supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An
unofficial fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this
number.

Any inquiry of a general nature or relating to the status of this application or proceeding
should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
3/7/02

MARY K. ZEMAN
PRIMARY EXAMINER